NHS Circular:
PCA (P)(2024) 36

Chief Medical Officer Directorate
Pharmacy and Medicines Division

Scottish Government
Riaghaltas na h-Alba
gov.scot

Dear Colleague

SERIOUS SHORTAGE PROTOCOL: ESTRADOT® (ESTRADIOL) 75 MICROGRAMS / 24 HOURS TRANSDERMAL PATCH

Purpose

1. To advise of a Serious Shortage Protocol (SSP) in place for Estradot® (estradiol) 75 micrograms / 24 hours transdermal patch, from 19 December 2024 to 19 January 2025.

Background

2. Changes made to the Human Medicines Regulations 2012 and the NHS (Pharmaceutical Services) (Scotland) Regulations 2009, the latter of which became effective from 31 October 2019, allow the use of Serious Shortage Protocols (SSPs).

3. An SSP is an additional tool to manage and mitigate medication shortages and may be used when other measures have been exhausted or are likely to be ineffective. There are two types of SSP; one that covers prescription only medicines and another that covers pharmacy and general sales list medicines and appliances.

4. Each SSP is individually developed and authorised clinically, to enable community pharmacists and dispensing doctors to dispense a different strength or formulation or alternative medicine or appliances in accordance with the protocol, rather than having to refer prescribing decisions back to the original prescriber. These protocols are time limited.

5. Community pharmacists are expected to use their professional skill and judgement to decide whether it is reasonable and appropriate to substitute a person's prescribed medicine using the SSP. The person will also have to agree to the alternative supply.

24 December 2024

Addresses

For action
Chief Executives, NHS Boards
Director Practitioner Services, NHS NSS

For information
Directors of Pharmacy
NHS Medical Directors

Enquiries to:

Pharmacy Team
1st Floor East Rear
St Andrew's House
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Email:
PharmacyTeam@gov.scot

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6. Certain classes of medicines, for example cytotoxic medicines, biologics, anti-epileptic medicines and certain antipsychotic medicines, are not considered to be suitable for SSPs due to concerns about ensuring bioequivalence. In these cases, people should be referred back to the prescriber for any decision about their treatment before any therapeutic or generic alternative is supplied.

7. To assist in alleviating the current supply issues with a number of Hormone Replacement Therapy (HRT) products availability, various UK-wide SSPs have been issued by the Department for Health and Social Care (DHSC), in consultation with the Scottish Government. The DHSC frequently reviews which HRT products should be under an SSP and for how long they need to be in place.

8. The addition of new SSPs and any amendments or extensions to existing SSPs are documented on the NHS Business Services Authority website using the following link: Serious shortage protocols (SSPs) | NHSBSA.

Medicine supply situation requiring the use of an SSP

9. A supply issue with Estradot® (estradiol) 75 micrograms / 24 hours transdermal patch has been identified. In order to manage stock supplies fairly and effectively, there is a UK-wide SSP in place, which allows community pharmacists to substitute a prescription for this product with the same quantity of Estraderm MX® (estradiol) 75 micrograms / 24 hours transdermal patch **or** Evorel® (estradiol) 75 micrograms / 24 hours transdermal patch. This SSP can be accessed using the following link: SSP080 Estradot 75mcg patches SIGNED.pdf.

Operational overview

10. Between 19 December 2024 and 19 January 2025, for patients presenting with an NHS or private prescription for a supply of Estradot® (estradiol) 75 micrograms / 24 hours transdermal patch, community pharmacists may substitute this product with the **same quantity** of Evorel® 75 micrograms / 24 hours transdermal patch **or** Estraderm MX® 75 micrograms / 24 hours transdermal patch, for eligible patients, in accordance with this SSP.

11. This protocol does **not** allow for the quantity supplied to be less than the number of days prescribed on the original prescription.

12. Community pharmacists are asked to review and familiarise themselves with the scope and the clinical situation to which this SSP applies, as outlined in the guidance provided within SSP 080.

13. **When a substitution is made, pharmacists need to ensure that the patient's prescriber and/or GP practice is notified in accordance with this SSP**.

14. Community pharmacists are asked to ensure that patients who are supplied in accordance with this SSP are counselled by the pharmacist with regards to monitoring and managing potential side effects, such as:
    - Vaginal 'breakthrough bleeding';
    - Irritation caused by wearing a different patch to one they are used to;

- Patches coming off or not adhering properly.

15. Patients who experience persistent side effects from alternative patches supplied in accordance with this SSP should be promptly referred back to their prescriber.

16. If a patient or their carer declines to receive the medicine under this SSP, the pharmacist should use their professional judgement to determine if other courses of action are appropriate whilst taking into consideration wider supply issues. If this does not address their concerns, the patient should be referred back to their prescriber.

17. Similarly, if a patient does not meet the criteria within this SSP then they should be referred back to their prescriber promptly.

18. This SSP 080 only applies to prescriptions for Estradot® 75 micrograms / 24 hours transdermal patch. Supply in accordance with this SSP only allows supply of a specific substitution up to the duration of treatment prescribed. However, if the pharmacist thinks that an alternative product, would be suitable for the patient they should either contact the prescriber to discuss this (with the patient's consent) or direct the patient back to the prescriber.

Additional information

19. Please see links for further advice on alternative hormone replacement therapies:

- CKS Hormone replacement therapy
- British Menopause Society – HRT preparations and equivalent alternatives

20. Please see the Specialist Pharmacy Service (SPS) website for advice on prescribing and availability of HRT products:

- Prescribing available HRT products – SPS - Specialist Pharmacy Service

Supporting information on notifying other healthcare professionals

21. Any items supplied in accordance with an SSP in response to an NHS prescription also needs to be supplied in accordance with NHS Pharmaceutical and Local Pharmaceutical Services Regulations.

22. Those Regulations provide that where a therapeutic equivalent is supplied, a pharmacist will need to inform a patient's GP practice. This would generally be expected within the next working day, but further guidance would be given in any case where this applied.

23. Where a different quantity, an alternative pharmaceutical form, an alternative strength or a generic equivalent is provided, it may not always be necessary that the patient's prescriber is informed, as the existence of the SSP may be enough for the prescriber to be aware that these changes in dispensing may take place, unless national arrangements agreed with the relevant representative bodies state

otherwise. However, guidance may be issued on particular SSPs to indicate that prescribers should be informed of any patients that receive supply under it.

Fees and Endorsements

24. When an SSP is introduced, the pharmacist should use the Other endorsement function quoting SSP and the relevant reference number – in this case add SSP 080. A community pharmacy contractor will receive a multiplier per item of 5 (x5), via the dispensing pool, for any necessary supply in accordance with SSPs. Endorsements must be made in line with the SSP to be eligible for payment.

25. The paper form should be endorsed PMR with details added of what was supplied as well as 'SSP 080' annotated. This is to ensure accurate reimbursement for non-barcoded forms or where an electronic claim message is unavailable.

Enquiries

26. For any queries on the detail of this SSP, please contact the Scottish Government Pharmacy Team at PharmacyTeam@gov.scot.

Action

27. **Health Boards are asked to note the contents of this Circular and to bring it to the attention of community pharmacy contractors on their Pharmaceutical Lists and Area Pharmaceutical Committees. This Circular should also be brought to the attention of General Practices.**

Yours sincerely

Alison Strath
Chief Pharmaceutical Officer